

## A LANCET DEVICE

### BACKGROUND OF THE INVENTION

#### Claim of Priority

The present application is a continuation-in-part application of previously filed, now pending application having Serial No. 10/134,995, filed on April 29, 2002.

#### Field of the Invention

The present invention relates to a lancet device preferably configured to provide a single use, and in all embodiments configured to substantially shield and protect a piercing tip thereof before and after use, while providing for accurate and effective piercing engagement of a patient's skin when appropriate. Furthermore, the present lancet device does not require complex and/or difficult to manipulate cocking and is structured such that the device is rendered in-operative after a single use.

### DESCRIPTION OF THE RELATED ART

Lancets are commonly utilized instruments which are employed both in hospitals and other medical facilities, as well as by private individuals, such as diabetics, in order to prick or pierce a patient's skin, typically on a finger of a patient,

1       thereby leading to the generation of a blood sample which can be  
2       collected for testing. Because of the wide spread use of such  
3       lancets, there are a variety of lancet devices which are  
4       available for utilization by patients and/or practitioners in a  
5       variety of different circumstances.

6             For example, a typical lancet may merely include a housing  
7       with a sharp piercing tip that is pushed into the patient's  
8       skin. More commonly, however, lancet devices, which house a  
9       piercing tip and/or a lancet, have been developed which  
10      effectively encase and fire the lancet into the patient's skin,  
11      thereby eliminating the need for the person taking the sample to  
12      actually push the lancet tip into the skin.

13            Within the various types of specialized lancet devices, one  
14      variety are typically configured for multiple and/or repeated  
15      uses, while another category is particularly configured for  
16      single use, after which the entire device is disposed of.  
17      Looking in particular to the single use, disposable lancet  
18      devices, such devices typically include a housing which contains  
19      and directs or drives a piercing tip into the patient's skin,  
20      and which is disposed of along with the used lancet. Naturally,  
21      so as to make such disposable devices cost effective for  
22      frequent use, such devices tend to be rather simplistic in  
23      nature providing only a sufficient mechanism for firing, and not  
24      overly complicating the design so as to minimize that cost.

25            While existing single use devices are generally effective

1 for achieving the piercing of the skin required for effective  
2 operation, such single use, disposable devices typically do not  
3 incorporate a large number of safety features to ensure the safe  
4 use and disposal of the device. For example, one primary area  
5 of safety which must be addressed with all lancet devices  
6 pertains to the purposeful and/or inadvertent reuse of a  
7 contaminated lancet. Unfortunately, most currently available  
8 single use lancet devices are configured such that after a use  
9 thereof has been achieved, it is possible for a patient to re-  
10 cock the device, thereby allowing for a subsequent,  
11 inappropriate use.

12 As a result, it would be highly beneficial to provide a  
13 single use lancet device which is substantially compact and  
14 disposable, can be manufactured in a substantially cost  
15 effective manner, and which nevertheless is substantially safe  
16 to utilize, affirmatively preventing re-use, once contaminated.

17 A further drawback associated with conventionally employed  
18 single use lancet devices is that they can often be difficult  
19 and/or complicated for elderly and/or impaired individuals to  
20 manipulate in order to achieve effective use. In particular,  
21 such existing devices often require a user to perform a number  
22 of different actions, including one to cock and thereby prepare  
23 the device for use, and another to actually fire the device. As  
24 can be appreciated, those procedures, even in the simplest form,  
25 can sometimes be complex and/or difficult to effectively achieve

1 on a small compact device by certain individuals, and especially  
2 those individuals performing self testing who necessarily only  
3 have one hand to use to manipulate the device. Indeed, to avoid  
4 these complexities, some manufactures have turned to the use of  
5 pre-cocked and ready to use devices, however, this can often  
6 result in misfires and/or pre-fires of the lancet such that a  
7 certain of percentage of the lancet devices are not usable.

8 As a result, it would also be beneficial to provide a  
9 lancet device, which whether single use and/or multiple use,  
10 could be very simplistic and effective to employee, not  
11 requiring a series of often complex activities to be perform in  
12 order to prepare the lancet for use and in order to actually  
13 utilize the lancet. Still, however, such a device should not  
14 comprise safety in the prevention of inadvertent use and/or re-  
15 use in exchange for the simplistic use, but rather should  
16 effectively coordinate all such beneficial characteristics. It  
17 would also be beneficial such a device could be effectively and  
18 cost effectively manufacture so as to make it available and  
19 affordable to a large variety of users, including home users.

#### 20 21 SUMMARY OF THE INVENTION

22 The present invention relates to a lancet device, and  
23 preferably a single use lancet device, utilized so as to  
24 effectively pierce a patient's skin and result in bleeding for  
25 subsequent sample collection. The lancet device of the present

1 invention preferably includes a housing having an at least  
2 partially open interior. Furthermore, a lancet is movably  
3 disposed relative to the housing and includes a piercing tip  
4 which ultimately will penetrate the patient's skin. Similarly,  
5 a biasing assembly is interposed between the lancet and the  
6 housing. The biasing assembly engages the lancet and functions  
7 to urge the lancet into its piercing orientation, when  
8 appropriate.

9 The lancet device of the present invention also includes a  
10 cocking seat. The cocking seat is structured to engage the  
11 lancet and retain the lancet against the force of the biasing  
12 assembly so as to establish a potential energy of the biasing  
13 assembly. In the preferred embodiment, the user's finger and/or  
14 another body part which is to be pierced, engages the cocking  
15 seat and thereby pushes the cocking seat and the lancet until it  
16 ultimately engages a release assembly that extends into the  
17 housing. In alternate embodiments, the cocking seat is  
18 integrally or separately disposed relative to the housing to  
19 retain the lancet against the force of a biasing element until  
20 released by an actuatable release assembly. The release assembly  
21 is structured to disengage the lancet from the cocking seat such  
22 that the potential energy of the biasing assembly drives the  
23 piercing tip of the lancet at least temporarily into its  
24 piercing orientation. As a result, in one illustrated  
25 embodiment, as the cocking seat moves the lancet, simultaneously

1 cocking it and moving it into its engaging relation with the  
2 release element for effective actuation and firing thereof to  
3 pierce the skin of the patient, while in another embodiment, the  
4 lancet device is "pre-cocked".

5 These and other features and advantages of the present  
6 invention will become more clear when the drawings as well as  
7 the detailed description are taken into consideration.

8  
9 BRIEF DESCRIPTION OF THE DRAWINGS

10 For a fuller understanding of the nature of the present  
11 invention, reference should be had to the following detailed  
12 description taken in connection with the accompanying drawings  
13 in which:

14 Figure 1 is a side cross-sectional view of a preferred  
15 embodiment of the lancet device of the present invention in an  
16 un-used orientation;

17 Figure 2 is a side cross-section view of the embodiment of  
18 Figure 1 in a substantially cocked and immanent to release  
19 orientation;

20 Figure 3 is a side cross-sectional view of a further  
21 embodiment of the lancet device of the present invention;

22 Figure 4 is an exploded view of the lancet device and  
23 cocking seat of a preferred embodiment of the present invention;

24 Figure 5 is a side cross-section view of still another  
25 embodiment of the lancet device of the present invention

1 illustrating a re-usable configuration thereof; and

2 Figure 6 is a side cross-section view of another embodiment  
3 of the lancet device of the present invention illustrating a  
4 fixed cocking seat.

5 Like reference numerals refer to like parts throughout the  
6 several views of the drawings.

7  
8 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

9 Shown throughout the Figures, the present invention is  
10 directed towards a lancet device, generally indicated as 10. In  
11 one embodiment of the present invention, as illustrated in  
12 Figures 1 through 3 and 6 the lancet device 10 is preferably a  
13 single use device such that after it is utilized for the first  
14 and only time it is configured so as to prevent subsequent use.  
15 Ultimately, however, as illustrated in Figure 5, a re-usable  
16 configuration may be provided.

17 Looking specifically to the Figures, the lancet device of  
18 the present preferably includes a housing 20. The housing 20  
19 includes an at least partially open interior 22 and can be made  
20 of any variety materials, but preferably will be formed of a  
21 molded plastic type material for ease of manufacture and  
22 minimization of cost. Also in the preferred embodiment, the  
23 housing 20 preferably includes an open end 26, which may  
24 represent a general front of the lancet device 10, and may  
25 include any variety of axial configurations, including a square,

1 triangle, oval, circle, etc., although a generally elongated,  
2 longitudinal configuration as illustrated in the Figures is  
3 preferred in conjunction therewith.

4 The lancet device 10 further includes a lancet 40 movably  
5 disposed at least partially within the housing 20 and including  
6 a piercing tip 42. In the single use embodiment of Figures 1  
7 through 3 and 6 the lancet 40 is a single integral unit as  
8 shown. Alternatively, as illustrated in the embodiment of  
9 Figure 5, what is referred to as a lancet in the claims may  
10 include a lancet body 40' from which the piercing tip 42  
11 extends, as well as a lancet receiving assembly 41, into which  
12 the lancet body 40' is disposed for movable retention. In such  
13 an embodiment, each time the lancet device 10 is to be re-used,  
14 a new lancet body 40' with piercing tip 42 is disposed within  
15 the lancet receiving assembly 41. In either embodiment,  
16 however, the lancet is movably disposed within the housing 20.

17 Preferably the lancet engages a biasing assembly also  
18 preferably disposed within the housing 20. In the illustrated  
19 preferred embodiments, the biasing assembly includes a biasing  
20 element 50 such as a metal or plastic spring. Preferably, the  
21 biasing element 50 is interposed between the lancet 40 and a  
22 rear end 55, 55' of the housing 20. The rear end 55, 55' may be  
23 unitary or separate from the housing 20. Moreover, positioned  
24 so as to engage the lancet 40 and retain it under the tension of  
25 the biasing assembly 50 is a cocking seat 30. In particular,



1 the cocking seat 30 is structured to engage the lancet 40 and  
2 retain the lancet 40 against a force of the biasing assembly 50  
3 so as to maintain a potential energy of the biasing assembly 50.  
4 In some illustrated embodiments, and as best seen in Figure 2,  
5 the cocking seat 30 urges the lancet 40 towards the rear end of  
6 the lancet housing 20, thereby resulting in a compression of the  
7 biasing assembly 50 and an increase in the potential energy  
8 thereof. Further, so as to maintain effectively appropriate  
9 alignment of the lancet and the cocking seat 30 as they are  
10 moving relative to the housing 20, in the preferred embodiment,  
11 a guide track assembly 24, 32 may be provided between the  
12 cocking seat 30 and the housing 20.

13 In the preferred, illustrated embodiments, an engagement  
14 assembly 34, 45 is provided and preferably interposed between  
15 the cocking seat 30 and the lancet 40 so as to maintain moving  
16 engagement between the lancet 40 and the cocking seat 30 until  
17 they are disengaged, as will be described. In the illustrated  
18 embodiments, the engagement assembly includes an engagement  
19 element 45 that extends from lancet 40 into effectively  
20 retained, engaging relation with a retention lip 34 on the  
21 cocking seat 30. As a result, as the cocking seat 30 moves  
22 inward towards the rear end 55 of the housing 20, the effective  
23 engagement between the engagement element 45 and the retention  
24 lip 34 results in movement of the lancet 40 in unison with the  
25 cocking seat 30. In this regard, it is understood that a

1 variety of different engagement assemblies, including one in  
2 which the engagement element extends from the cocking seat into  
3 engagement with a corresponding retention lip on the lancet, may  
4 also effectively be provided, the engagement assembly being  
5 configured so as to provide for effective substantially,  
6 although not necessarily completely, unitary movement between  
7 the lancet 40 and the cocking seat 30 until effective release  
8 thereby, as will be described. Further, in yet another  
9 embodiment, as seen in Figure 6, the cocking seat may be pre-  
10 introduced into housing, or be integrally formed with or secured  
11 to the housing 20 such that the lancet 40 is effectively  
12 maintained under a tension of the biasing assembly until  
13 released by a moveable release assembly.

14 In particular, the present lancet device 10 further  
15 includes a release element 56. In the illustrated embodiments,  
16 the engagement element 45 of the engagement assembly preferably  
17 has a generally flexible and/or resilient characteristic  
18 relative to the lancet 40, and/or as will be described, includes  
19 a single use pivot 46. As a result, when the cocking seat 30  
20 and therefore the lancet 40 are urged sufficiently into an  
21 interior 22 of housing 20, the release element 56 which also at  
22 least partially extends into an interior of the housing 20 when  
23 firing is desired, serves to engage the engagement element 45,  
24 and ultimately causes upward movement thereof for disengagement  
25 between the engagement element 45 and a retention lip 34.

1 Moreover, this disengagement is achieved after a substantial  
2 amount of potential energy has been achieved in the biasing  
3 assembly 50. As a result, disengagement between the lancet 40  
4 and the cocking seat 30 results in the lancet 40 moving relative  
5 to the cocking seat 30 under a force achieved by the potential  
6 energy stored in the biasing assembly 50. The guide track 32  
7 may also serve to guide generally linear movement of the lancet  
8 40 relative to the cocking seat 30, as the lancet 40 moves to  
9 the open interior 31 of the cocking seat 30 and ultimately  
10 protrudes through an opening 37 in an exterior end 36 of the  
11 cocking seat 30.

12 Looking further to the single use pivot 46, this may be  
13 defined by a reduce thickness region in the segment that  
14 ultimately defines the engagement element. The pivot 46 may be  
15 seen to define a breakable hinge, and is configured such that  
16 when the release element 56 engages the engagement element 45,  
17 the engagement element 45 pivots on said pivot point and cannot  
18 generally return to its pre-pivoted orientation. As a result,  
19 even if re-positioning of the engagement element relative to the  
20 cocking seat was attempted, the necessary engagement could not  
21 be achieved as the reduced thickness portion snaps and or  
22 deforms to prevent such re-positioning. A single use of the  
23 device is therefor further ensured.

24 As previously indicated, the cocking seat 30, and  
25 preferably the exterior end 36 of the cocking seat 30 may be

1 configured to engage a patient, at least in a general vicinity  
2 of a portion to be pierced. Furthermore, in the preferred,  
3 illustrated embodiment, the opening 37 at the end 36 of the  
4 cocking seat 30 is preferably aligned with a specific location  
5 to be pierced, such as on a tip of the finger. That portion of  
6 the body, such as the finger, is thereby utilized as an abutment  
7 on one of the lancet device 10, while a corresponding support  
8 element, such as another finger or a thumb of the patient, or a  
9 hand of a medical practitioner or other user, or a solid  
10 surface, engages the housing 20 of the lancet device 10. In  
11 this regard, as either or both the body section and the support  
12 element are moved towards one another such that a spacing  
13 therebetween is reduced, the moveable cocking seat 30 moves  
14 further into the housing 20 until ultimately the engagement  
15 element 45 engages and is released by the released element 56.  
16 Once this release is achieved, the lancet 40 moves relative to  
17 the cocking seat 30 passing, therethrough such that its piercing  
18 tip 42 protrudes from the open end 37 of the cocking seat 30 and  
19 piercingly engages the patient's skin. Therefore, in the  
20 embodiments of Figures 1 and 2 the cocking movement directly  
21 results in firing of the lancet 40, requiring only a single,  
22 fluid movement to effectively utilize the present lancet device  
23 10. Looking in further detailed to the previous description, it  
24 is understood that the effective firing can be achieved either  
25 by moving the portion of the patient, such as their finger

1 inward against a fixed support element, by moving a support  
2 element towards a fixed portion of the body to be pierced and/or  
3 by compressing both towards one another.

4 Turning to the embodiment of Figures 3 and 6, it is also  
5 understood, that for further safety reasons, if desired, the  
6 release element 56 may not necessarily be positioned at all  
7 times in an appropriate location to effectively release the  
8 lancet 40 from its engagement with the cocking seat 30. For  
9 example, in the embodiment of Figure 3 a stopper 25 is position  
10 such that movement of the cocking seat 30 and therefore the  
11 lancet 40 towards the rear end 55' will not result in a  
12 sufficient travel distance such that the engagement element 45  
13 is released by the release element 56. Similarly, in the  
14 embodiment of Figure 6 wherein the cocking seat forms part of  
15 the housing and the lancet is re pre-cocked, but does not  
16 automatically fire. Rather, in these illustrated embodiments  
17 actuation of the rear end 55' inwardly is required so as to  
18 effectively move the release element 56 into a position where it  
19 may engage the engagement element 45 and provide for appropriate  
20 release of the lancet 40 from the cocking seat 30. Also in the  
21 embodiment of Figure 3 a spring or a stopper may be provided so  
22 as to also restrict movement of the actuation element 55', as it  
23 is ultimately preferred that actuation thereof be utilized only  
24 so as to effectively position the release element 56 in a  
25 position and orientation such that the previous or subsequent

1 movement of the cocking seat 30 and/or the housing 20 in the  
2 manner previously described for cocking and firing results in  
3 the releasing engagement between the release element 56 and the  
4 engagement element 45. Also on such embodiments is recognized  
5 that a variety of different actuation assemblies 55' may be  
6 effectively provided so as to position the release element 56 in  
7 its appropriate position to release the lancet. For example, a  
8 side, spring loaded button and/or resilient button may be  
9 provided such that the release element 56 is retained at least  
10 partially out of the housing and/or out of engaging relation  
11 with the engagement element 45 until it is actuated and moved at  
12 least partially into the interior of the housing 20.  
13 Furthermore, as evidenced by the embodiment of Figure 6,  
14 additional structure may be provided so as to cock the lancet  
15 device, or it may be sold pre-cocked with the cocking seat 30  
16 may be pre-positioned in an appropriate position to allow  
17 actuation of the release element 56 to effectively disengage the  
18 engagement element 45 from the cocking seat 30. As mentioned, in  
19 such an embodiment, the cocking seat 30 can be retained in  
20 position relative to the housing or can merely be integrally  
21 formed with and/or secured to the housing 20, thus eliminating  
22 the need to push in the cocking seat 30 and allowing for mere  
23 actuation of the release element 56 to result in disengagement  
24 of a properly positioned engagement element.

25 Looking again to Figure 1, further features that may be

1 provided with the present invention may be the inclusion of a  
2 cover element 43 which is structured to protect and shield the  
3 piercing tip 42 of the lancet 40 prior to use. The cover  
4 element 43 preferably extends out from the open interior 31 of  
5 the cocking seat 30, out through the opening 37 so as to be  
6 effectively grasped by a user for removal thereof when preparing  
7 the lancet device 10 for use. Alternately, and exterior cover  
8 that covers the cocking seat and/or surrounds the piercing tip  
9 may also be provided. It is also noted, that the cocking seat  
10 30 is configured such that even when the cover element 43 is  
11 removed, the piercing end 42 is protected and/or shielded within  
12 the interior 31 thereof unless and until use. Indeed, it is  
13 only when the driving force of the biasing assembly 50 urges the  
14 lancet's movement relative to the cocking seat 30 that the  
15 piercing tip 42 temporarily passes through the opening 37.  
16 Still, as a final safety measure, although a single biasing  
17 assembly 50 may be sufficient so as to both drive the lancet 40  
18 into its piercing orientation and so as to generally retract  
19 back into its protective shielding within the cocking seat 30,  
20 in some embodiments a secondary biasing assembly 52 may also be  
21 positioned and interposed between the lancet 40 and the cocking  
22 seat 30, the secondary biasing assembly 52 being structured and  
23 disposed so as to not hinder movement of the piercing tip 42  
24 into its piercing orientation, but so as to effectively retract  
25 the lancet 40 back into its protective containment within the

1       cocking seat 30.   Moreover, that retraction should not be  
2       sufficient so as to return the lancet 40 into its engagement  
3       relation with the cocking seat 30 for unitary movement  
4       therebetween.

5               Since many modifications, variations and changes in detail  
6       can be made to the described preferred embodiment of the  
7       invention, it is intended that all matters in the foregoing  
8       description and shown in the accompanying drawings be  
9       interpreted as illustrative and not in a limiting sense. Thus,  
10      the scope of the invention should be determined by the appended  
11      claims and their legal equivalents.

12             Now that the invention has been described,